

AMENDMENTS TO THE CLAIMS

This listing of claims will replace all prior versions and listings of claims in the application.

Listing of Claims:

1-57. (Canceled)

58. (Currently Amended) A container for storing, sterilizing, and admixing medical solutions comprising:

a first chamber;

a second chamber; and

a peelable seal separating the first chamber from the second chamber;

wherein the container ~~is resistant to leaching~~ leaches one or more of: (i) less than 0.11 µg/ml of a semi-volatile compound; (ii) less than 0.023 µg/ml of aluminum; (iii) less than 5.6 µg/ml of an oligomeric propylene compound; and (iv) less than 5.6 µg/ml of an oligomeric ethylene vinyl acetate compound; into a lipid component contained and autoclaved in the container ~~greater than one or more of: (i) 0.11 µg/ml of a semi-volatile compound; (ii) 0.023 µg/ml of aluminum; (iii) 5.6 µg/ml of an oligomeric propylene compound; or (iv) 5.6 µg/ml of an oligomeric ethylene vinyl acetate compound.~~

59. (Previously Presented) The container of claim 58 wherein the container is constructed from a flexible plastic material.

60. (Previously Presented) The container of claim 59 wherein the flexible plastic material does not contain polyvinyl chloride.

61. (Previously Presented) The container of claim 60 wherein the flexible plastic material is a multilayer film.

62. (Previously Presented) The container of claim 61 wherein the multilayer film comprises four layers.

63. (Previously Presented) The container of claim 58 wherein the peelable seal is a heat sealed peelable seal.

64. (Previously Presented) The container of claim 63 wherein the peelable seal is an RF welded peelable seal.

65. (Previously Presented) The container of claim 59 wherein the flexible plastic material further comprises an RF responsive polymer layer composed of an ethylene vinyl acetate copolymer.

66. (Previously Presented) The container of claim 58 wherein the semi-volatile compound is selected from the group consisting of 2,6 di-t-butyl-4-methyl-phenol; 2, 6-di-t-butyl-4-ethylphenol; and 25-crown-5 ether.

67. (Currently Amended) The container of claim 66 wherein the container leaches less than 0.050 µg/ml ~~the concentration of 2, 6-di-t-butyl-4-methyl-phenol is less than 0.050 µg/ml.~~

68. (Currently Amended) The container of claim 66 wherein the container leaches less than 0.010 µg/ml ~~the concentration of 25-crown-5 ether is less than 0.010 µg/ml.~~

69. (Currently Amended) The container of claim 66 wherein the container leaches less than 0.010 µg/ml ~~the concentration of 2, 6-di-t-butyl-4-ethylphenol is less than 0.011 µg/ml.~~

70. (Currently Amended) A container and medical solution comprising:

a first chamber;

a second chamber;

a lipid component contained in one of the first and second chamber; and

a peelable seal separating the first chamber from the second chamber;

wherein the container ~~leaches~~ is resistant to leaching by the lipid component greater than one or more of:

- (i) less than 0.11 µg/ml of a semi-volatile compound;
- (ii) less than 0.023 µg/ml of aluminum;
- (iii) less than 5.6 µg/ml of an oligomeric propylene compound; ~~or~~ and
- (iv) less than 5.6 µg/ml of an oligomeric ethylene vinyl acetate compound,

into the lipid component when autoclaved.

71. (Previously Presented) The container and medical solution of claim 70 wherein the container is constructed from a flexible plastic material.

72. (Previously Presented) The container and medical solution of claim 71 wherein the flexible plastic material does not contain polyvinyl chloride.

73. (Previously Presented) The container and medical solution of claim 72 wherein the flexible plastic material is a multilayer film.

74. (Previously Presented) The container and medical solution of claim 73 wherein the multilayer film comprises four layers.

75. (Previously Presented) The container and medical solution of claim 70 wherein the peelable seal is a heat sealed peelable seal.

76. (Previously Presented) The container and medical solution of claim 75 wherein the peelable seal is an RF welded peelable seal.

77. (Previously Presented) The container and medical solution of claim 70 wherein the flexible plastic material further comprises an RF responsive polymer layer composed of an ethylene vinyl acetate copolymer.

78. (Previously Presented) The container and medical solution of claim 70 wherein the semi-volatile compound is selected from the group consisting of 2, 6 di-t-butyl-4-methyl-phenol; 2, 6-di-t-butyl-4-ethylphenol; and 25-crown-5 ether.

79. (Currently Amended) The container and medical solution of claim 78 wherein the container leaches less than 0.050 $\mu\text{g/ml}$ ~~the concentration of 2, 6-di-t-butyl-4-methyl-phenol is less than 0.050 $\mu\text{g/ml}$.~~

80. (Currently Amended) The container and medical solution of claim 78 wherein the container leaches less than 0.010 $\mu\text{g/ml}$ ~~the concentration of 25-crown-5 ether is less than 0.010 $\mu\text{g/ml}$.~~

81. (Currently Amended) The container and medical solution of claim 78 wherein the container leaches less than 0.011 $\mu\text{g/ml}$ ~~the concentration of 2, 6-di-t-butyl-4-ethylphenol is less than 0.011 $\mu\text{g/ml}$.~~

82. (Currently Amended) A medical product comprising:

a container having a first chamber;
a second chamber; and
a peelable seal separating the first chamber from the second chamber; and
a lipid component contained in one of the first and second chambers and having one or more of:

- (i) a semi-volatile compound concentration of less than 0.11 $\mu\text{g/ml}$;
- (ii) an aluminum concentration of less than 0.023 $\mu\text{g/ml}$;
- (iii) an oligomeric propylene concentration of less than 5.6 $\mu\text{g/ml}$; ~~or~~ and
- (iv) an oligomeric ethylene vinyl acetate concentration of less than 5.6 $\mu\text{g/ml}$,

~~before and after~~ the container and lipid component contained in one of the first and second chamber have been autoclaved.

83. (Previously Presented) The medical product of claim 82 wherein the container is constructed from a flexible plastic material.

84. (Previously Presented) The medical product of claim 83 wherein the flexible plastic material does not contain polyvinyl chloride.

85. (Previously Presented) The medical product of claim 84 wherein the flexible plastic material is a multilayer film.

86. (Previously Presented) The medical product of claim 85 wherein the multilayer film comprises four layers.

87. (Previously Presented) The medical product of claim 82 wherein the peelable seal is a heat sealed peelable seal.

88. (Previously Presented) The medical product of claim 87 wherein the peelable seal is an RF welded peelable seal.

89. (Previously Presented) The medical product of claim 82 wherein the flexible plastic material further comprises an RF responsive polymer layer composed of an ethylene vinyl acetate copolymer.

90. (Previously Presented) The medical product of claim 82 wherein the semi-volatile compound is selected from the group consisting of 2, 6 di-t-butyl-4-methyl-phenol; 2, 6-di-t-butyl-4-ethylphenol; and 25-crown-5 ether.

91. (Previously Presented) The medical product of claim 90 wherein the concentration of 2, 6-di-t-butyl-4-methyl-phenol is less than 0.050 µg/ml.

92. (Previously Presented) The medical product of claim 90 wherein the concentration of 25-crown-5 ether is less than 0.010 µg/ml.

93. (Previously Presented) The medical product of claim 90 wherein the concentration of 2, 6-di-t-butyl-4-ethylphenol is less than 0.011 µg/ml.

94. (Currently Amended) An autoclaved medical product comprising:

a container having a peelable seal separating a first and second chamber; and

a lipid component contained in one of the first and second chambers, the lipid component including ~~less than one or more of:~~ (i) less than 0.11 µg/ml of a semi-volatile compound; (ii) less than 0.023 µg/ml of aluminum; (iii) less than 5.6 µg/ml of an oligomeric propylene compound; ~~or and~~ (iv) less than 5.6 µg/ml of an oligomeric ethylene vinyl acetate compound.

95. (Previously Presented) The autoclaved medical product of claim 94 wherein the container is constructed from a flexible plastic material.

96. (Previously Presented) The autoclaved medical product of claim 95 wherein the flexible plastic material does not contain polyvinyl chloride.

97. (Previously Presented) The autoclaved medical product of claim 96 wherein the flexible plastic material is a multilayer film.

98. (Previously Presented) The autoclaved medical product of claim 97 wherein the multilayer film comprises four layers.

99. (Previously Presented) The autoclaved medical product of claim 94 wherein the peelable seal is a heat sealed peelable seal.

100. (Previously Presented) The autoclaved medical product of claim 99 wherein the peelable seal is an RF welded peelable seal.

101. (Previously Presented) The autoclaved medical product of claim 94 wherein the flexible plastic material further comprises an RF responsive polymer layer composed of an ethylene vinyl acetate copolymer.

102. (Previously Presented) The autoclaved medical product of claim 94 wherein the semi-volatile compound is selected from the group consisting of 2, 6 di-t-butyl-4-methyl-phenol; 2, 6-di-t-butyl-4-ethylphenol; and 25-crown-5 ether.

103. (Previously Presented) The autoclaved medical product of claim 102 wherein the concentration of 2, 6-di-t-butyl-4-methyl-phenol is less than 0.050 µg/ml.

104. (Previously Presented) The autoclaved medical product of claim 102 wherein the concentration of 25-crown-5 ether is less than 0.010 µg/ml.

105. (Previously Presented) The autoclaved medical product of claim 102 wherein the concentration of 2, 6-di-t-butyl-4-ethylphenol is less than 0.011 µg/ml.

106. (Currently Amended) A container for storing and admixing medical solutions comprising:

a first chamber containing a lipid component having ~~less than~~ one or more of: (i) less than 0.11 µg/ml of a semi-volatile compound; (ii) less than 0.023 µg/ml of aluminum; (iii) less than 5.6 µg/ml of an oligomeric propylene compound; ~~or~~ and (iv) less than 5.6 µg/ml of an oligomeric ethylene vinyl acetate compound;

a second chamber; and

a peelable seal separating the first chamber from the second chamber.

107. (Previously Presented) The container of claim 106 wherein the semi-volatile compound is selected from the group of 2,6 di-t-butyl-4-methyl-phenol; 2,6-di-t-butyl-4-ethylphenol; and 25-crown-5 ether.

108. (Previously Presented) The container of claim 107 wherein the predetermined concentration of 2,6-di-t-butyl-4-methyl-phenol is less than 0.050 µg/ml.

109. (Previously Presented) The container of claim 107 wherein the predetermined concentration of 2,6-di-t-butyl-4-ethylphenol is less than 0.011 µg/ml.

110. (Previously Presented) The container of claim 107 wherein the predetermined concentration of 25-crown-5 ether is less than 0.010 µg/ml.

111. (Previously Presented) The container of claim 106 wherein the lipid component includes less than 0.023 µg/ml of aluminum.

112. (Previously Presented) The container of claim 106 wherein the lipid component includes less than 5.6 µg/ml of an oligomeric propylene compound.

113. (Previously Presented) The container of claim 106 wherein the predetermined concentration is 5.6 µg/ml and the leached compound is oligomeric ethylene vinyl acetate.

114. (Previously Presented) The container of claim 106 wherein the container is constructed from a flexible plastic material.

115. (Previously Presented) The container of claim 114 wherein the flexible plastic material does not contain polyvinyl chloride.

116. (Previously Presented) The container of claim 115 wherein the flexible plastic material is a multilayer film.

117. (Previously Presented) The container of claim 116 wherein the multilayer film comprises four layers.

118. (Previously Presented) The container of claim 106 wherein the container is an autoclaved container.

119. (Previously Presented) The container of claim 106 wherein the peelable seal is a heat sealed peelable seal.

120. (Previously Presented) The container of claim 119 wherein the peelable seal is an RF welded peelable seal.

121. (Previously Presented) The container of claim 114 wherein the flexible plastic material further comprises an RF responsive polymer layer composed of an ethylene vinyl acetate copolymer.

122. (Previously Presented) The container of claim 121 wherein the lipid component includes less than 5.6 µg/ml of an oligomeric ethylene vinyl acetate compound.

123. (Withdrawn) A method of making a medical product comprising the steps of:

providing a flexible container having a first chamber, a second chamber and a peelable seal separating the first chamber from the second chamber;

introducing into one of the first and second chambers a lipid component;

autoclaving the flexible container and lipid component

wherein the lipid component after autoclaving has a semi-volatile compound concentration of less than 0.011 µg/ml.